IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

GAYNELL GRIER, et al., individually and on behalf of others similarly situated,	)	
Plaintiffs,	)	
and	)	Case No. 3:79-3107
	)	Judge Nixon
SANFORD BLOCH, et al., and all others similarly situated,	)	
Plaintiffs-Intervenors,	)	Class Action
v.	)	
M.D. GOETZ, JR., Commissioner, Tennessee Department of Finance and Administration, et al.,	)	
Defendants,	)	
and	)	
TENNESSEE ASSOCIATION OF HEALTH MAINTENANCE ORGANIZATIONS, et al.,	)	
Defendants-Intervenors.	)	

MEMORANDUM ORDER

Pending before the Court is Defendants' Motion to Approve the State's Proposed Revisions to the 2003 Consent Decree[1] (Doc. No. 1355), to which Plaintiffs have responded in opposition; and Plaintiffs' and Defendants' Motions to Clarify or Amend this Court's March 23,

[1] Terms used but not defined herein shall have the same meaning attributed to them in the Court's Memorandum (Doc. No. 1282).

2006 Order revising Paragraph C(7) of the 2003 Consent Decree (Doc. Nos. 1358, 1359).

Seven months after this Court's Memorandum opinion approving certain of the State's requested modifications to the 2003 Consent Decree, the parties have been unable to agree on the language of the majority of the revisions. The Court has reviewed both parties' proposed modifications to the 2003 Consent Decree and accompanying memoranda.[2] Accordingly, the Court APPROVES the modifications to which the parties have agreed. (See Doc. No. 1356 (highlighting agreed upon text in yellow).)[3] The Court APPROVES the remaining

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[2] Defendants assert that the Court should not consider Plaintiffs' proposed revisions because they are untimely. Defendants claim that they already altered their policies, procedures, and notices on January 1, 2006, and the Court should not require them to be changed. Defendants' argument is of little legal merit. The Court specifically requested Plaintiffs' proposals when it ordered "the parties to this action to submit revisions to the 2003 Consent Decree that are consistent with this Memorandum and this Court's previously issued Orders . . . ." (Doc. No. 1282 at 106) (emphasis added). Furthermore, Defendants were well-aware that any action they took to implement the Court's prior Orders was subject to this Court's approval of the Consent Decree. (See Doc. No. 1372, Ex. C) (acknowledging that State's action was based on "State's proposed modifications to the Grier Revised Consent Decree") (emphasis added). Importantly, Defendants chose to modify their policies and procedures before even meeting with Plaintiffs to discuss the specific modifications to the Decree. (See Letter, dated Dec. 15, 2006 from N. Moss to G. Bonnyman (stating that it was, in the State's view, more logical to discuss revisions to the Consent Decree after the State had completed revising its regulations).) Had Defendants submitted their proposed modifications shortly after this Court's November Memorandum, this Court would have considered the proposals immediately. Instead, Defendants, along with Plaintiffs, sought an extension of time to submit their modifications to the Court. (See Doc. No. 1331.) The delay in seeking approval of the modifications rests squarely with the parties, if not entirely with Defendants, and the consequences of Defendants' choice of so proceeding should be borne by them, not by Plaintiffs.

[3] Certain sentences and/or paragraphs were not highlighted in yellow, suggesting a disagreement between the parties. However, upon a review of the parties' supporting memoranda, there appeared to be no disagreement. (See, e.g., parenthetical in preamble describing several docket numbers, first sentence of Paragraph B(6)(c), Paragraph B(12), parenthetical in preamble of Paragraph C(1), and Paragraph C(16)(h)(i)(ii). Unless expressly discussed in Section I of this Memorandum Order, these sentences and/or paragraphs are also APPROVED.

modifications, as listed in *italics* in Section I infra. Although the reasons underlying the approval have been extensively outlined in this Court's Memorandum and Orders (Doc. Nos. 1246, 1248, 1256, 1261, 1282, 1328, 1342, 1347, 1345), the Court has further explained the reasons for its approval where necessary.

I. APPROVED MODIFICATIONS

1. Paragraph B(6)(c)

c. Notwithstanding this definition, a reasonable time required for a beneficiary to exhaust an administrative grievance or other informal process shall not be counted when determining a delay. Circumstances in which a beneficiary may be required to exhaust an administrative process before an appeal can be commenced and/or processed consist of the following:

i. Requests for a drug or service requiring prior authorization when prior authorization has not been sought;

ii. Requests for a drug or service by beneficiaries without a prescription or order for that drug or service; and

iii. Requests for a service or reimbursement where the enrollee has not yet requested such service or reimbursement from his/her MCC such that the service or reimbursement has been denied.

In addition, Defendants seek to require a beneficiary to exhaust an administrative process before an appeal can be commenced in two additional situations: (1) requests from beneficiaries

to change MCCs; and (2) requests from beneficiaries to change his/her lock-in pharmacy. This is the first time Defendants have raised these requests. Defendants have had ample opportunity to prove why an administrative process for these two additional situations is required, but they failed to do so.[4]

With regard to MCC change requests, Defendants' request in their motion to modify the 2003 Consent Decree was limited to the implementation of a reasonable set of geographic and/or clinical hardship criteria to determine when enrollees would be allowed to transfer between MCCs outside of defined open enrollment periods. (Doc. No. 1086 at 6.) The Court granted this request in its entirety in its very first Order, dated July 28, 2005, and did not modify or clarify this ruling. (Compare Doc. No. 1246 at 3 with Doc. Nos. 1248, 1256, 1261, 1282, 1328.) In contrast, there was no mention of the pharmacy lock-in change requests in Defendants' motion to modify the 2003 Consent Decree. (See Doc. No. 1086.) Accordingly, the Court's Orders are silent on this issue.

At no point during the parties' repeated requests for clarification (each and every one of which this Court entertained) did either party raise the idea of requiring beneficiaries to seek an administrative process before an appeal could be commenced for MCC or pharmacy lock-in change requests. Indeed, the Court only permitted Defendants to use an administrative process in situations regarding requests for drugs or services without prior authorization (Doc. No. 1282

[4] The Court notes that it did not specifically permit an administrative process for subparagraph "iii. Requests for a service or reimbursement where the enrollee has not yet requested such service or reimbursement from his/her MCC such that the service or reimbursement has been denied." Nevertheless, it is a subset of subparagraph "ii. requests for a drug or service by beneficiaries without a prescription or order for that drug or service." Therefore, an administrative process for situations described in subparagraph iii. is permissible for the same reasons outlined in this Court's previous Memorandum and Orders.

at 70-71), requests for drugs or services without a prescription or order (id. at 83), and the determination of excusable neglect when faced with a beneficiary's challenge to an eligibility category that should have been raised previously (id. at 78). As a result, Defendants did not present any proof as to why an administrative process would be required for MCC and pharmacy lock-in change requests. The Court finds Defendants' current motion to add these requests for modification into the final Consent Decree to be untimely.

Even so, the Court would have been willing to consider these requests at this late stage if Defendants had followed this Court's recommendation to create guidelines for what constitutes "reasonable promptness." The Court's permission to create an administrative process prior to the processing of an appeal in certain situations was based on 42 C.F.R. § 431.220(a), which requires that once an enrollee has made a claim for services, such claim be treated with "reasonable promptness." The Court declined to rule on what constitutes "reasonable promptness" for two reasons. First, no proof of what constitutes "reasonable promptness" was presented. Second, "reasonable promptness" means different things in different situations. As a result, the Court recommended the State, upon consultation with the other parties to this action, create guidelines to flesh out the meaning of "reasonable promptness." The purpose of such guidelines is to educate TennCare beneficiaries as to how long they must wait before continuing or beginning an appeal.

Defendants have not presented any evidence that they have created such guidelines. Furthermore, they have opposed -- in its entirety -- the definition of "reasonable promptness" that the Plaintiffs have proposed in Paragraph B(6)(c). While Defendants strongly object to Plaintiffs' proposal and enumerate in detail why Plaintiffs' proposal is unworkable (see Doc. No.

1372, Killingsworth Supp. Decl. at 10-13), Defendants have not countered with a specific definition of their own. Instead, Defendants maintain that "[i]ncluding specific deadlines and timeframes for completing administrative or other informal processes in the Decree severally [sic] curtails the flexibility of state officials in administering the program and does not allow officials to adapt the processes to changed circumstances as time and experience provides more understanding on how the processes could better function." (Doc. No. 1374.) The Court did not mandate that a specific definition for "reasonable promptness" be included in the Decree, it only recommended that Defendants create guidelines. Having ignored (a) this Court's Orders regarding the specific instances when an administrative process can be used, and (b) this Court's recommendation regarding the creation of a definition of "reasonable promptness," Defendants cannot now expect this Court to rubber stamp proposed modifications to the 2003 Consent Decree that were never raised in their motion to modify or in subsequent clarification requests. Thus, Defendants' proposal is REJECTED in part and APPROVED in part.

In their proposal, Plaintiffs seek to define what constitutes "reasonable promptness," and have included specific timeframes in their proposal. The Court is sympathetic to Plaintiffs' desire to include a specific definition of what constitutes "reasonable promptness" in the Consent Decree. Nevertheless, the Court did not require such a definition to be included, and again declines to do so at this stage when there has been no proof as to what would constitute "reasonable promptness" in the vastly different situations in which the Court has permitted an administrative process to be used before the commencement of an appeal. As a result, Plaintiffs' proposed definition of what constitutes "reasonable promptness" is REJECTED.

2. Paragraph B(18)

18. As referred to in this order in the context of TennCare medical services appeals, "valid factual dispute" means any dispute that, if resolved in favor of the enrollee, would entitle the enrollee to coverage of the medical services.

Plaintiffs' proposed additions to Paragraph B(18) are unnecessary. The majority of the additions are direct quotes from this Court's Memorandum. (See Doc. No. 1282 at 74-78.) Defendants are bound to both this Court's Memorandum and the Consent Decree, and the inclusion of this Court's discussion on the issue of valid factual dispute in the Consent Decree is redundant.

Plaintiffs, however, raise an additional point that merits a brief discussion. Plaintiffs complaint is not really with the State's definition of a valid factual dispute, but with Public Necessity Rule 12-13-13-.11(3)(d)(2). This rule states that in order to establish a valid factual dispute, a TennCare enrollee must provide his or her name, social security number or TennCare ID number, address and phone, identification of the service or item that is the subject of the adverse action, and the reason for the appeal, including any factual error the enrollee believes TennCare or the MCC made. Plaintiffs argue that the State does not need identifying information in order to determine whether a valid factual dispute exists. The Court begs to differ. Plaintiffs complain that the State is not providing sufficient information in their notices for TennCare enrollees to adequately respond. The Court addresses those issues below, but let it be clear: the appeals process is a two-way street, and the State cannot bear the entire burden of obtaining and providing information required to resolve appeals. TennCare enrollees bear the

minimum responsibility of identifying themselves and explaining why they are appealing. The Court's reference in its Memorandum that an enrollee's appeal must be deemed to contain a valid factual dispute if an enrollee states that "I am appealing because I did not get my medicine or treatment" is not to the contrary. Rather, the Court was simply explaining that an enrollee does not have to give detailed reasons in order for the appeal to present a valid factual dispute. Moreover, the Court is satisfied with Assistant TennCare Commissioner Patti Killingsworth's explanation that to date, no appeal has been dismissed for failure to include identifying information because the State exercises due diligence in obtaining such information whenever possible.

In sum, Plaintiffs' proposed revision to Paragraph B(18) is REJECTED and Defendants' proposed revision is APPROVED.

3. Plaintiffs' Proposed New Subsection (iv) to Paragraph C(1)(b)

Paragraph C(1)(b) provides the elements that must be included in a notice of an adverse action. Plaintiffs suggest that in addition to the existing requirements, Defendants must also "iv. Provide reasons for the weight given to the treating physician, see Paragraph C(7)(b)(vii), infra . . . ." The Court disagrees. The weight given to the treating physician is specific to decisions regarding medical services, and need not be included in all notices, such as notices regarding a denial of prior authorization of a drug. See discussion of Paragraph C(7)(b), infra. Accordingly, Plaintiffs' proposed new subsection (iv) to Paragraph C(1)(b) is REJECTED.

4. Paragraph C(1)(e)

e. Content of Pharmaceutical Notices. Due to the highly automated procedures for prior authorization of medications, the need for an emergency 72-hour supply of prescribed medications, the ongoing changes and refinements to the State's preferred drug list, and implementation of "soft" pharmacy benefit limits, pharmaceutical notices must be treated differently from other medical services.

(i) If the service at issue is a prescription drug for which a request for prior authorization has been denied, the defendants shall issue a notice through their PBM. Although this notice may not require all the information required under C(1)(a)-(b), it must meet the minimum requirements for a meaningful notice required under 42 C.F.R. §§ 431.206-210. Meaningful notice for the purposes of this subsection requires an identification of the medication prescribed, the reason(s) for the denial, and if such reason is medical necessity, the reason(s) why the medication is not medically necessary, and the regulations to support the denial of prior authorization. The statement of reason(s) that the medication is not medically necessary may be indicated by reference to a list of pharmacy edits used by the TennCare PBM.

(ii) If the service at issue is a prescription drug for which prior authorization has not been sought, defendants shall issue a preprinted notice through their participating pharmacies that informs enrollees of (a) the need to obtain prior authorization, (b) how the enrollee and his or her provider can seek prior authorization, (c) what must be shown to obtain an emergency 72-hour supply of

prescribed medication, and (d) the administrative process they must exhaust before they may appeal. Attached as part of Collective Exhibit A to this order are sample notices that satisfy the requirements of this provision, and that shall be used by the defendants as a template for the notices they issue.

The dispute over Paragraph C(1)(e) centers around the content of the notice informing the enrollee of the denial of prior authorization of a prescription drug. Plaintiffs claim that in addition to the identity of the medication, the reason why a drug is not medically necessary and the regulatory authority on which the denial is based, 42 C.F.R. § 431.210 requires Defendants to include the identity of the prescriber and the dosage of the medication. In the alternative, Plaintiffs argue that Paragraphs C(1)(a) and (b) of the 2003 Consent Decree required these two pieces of information to be included in the notice. Defendants object to Plaintiffs' suggestion that the identity of the prescriber, the dosage of the medication, and the reason why a drug is not medically necessary should be included in the notice. Defendants further assert that they have cited sufficient regulations in the notices, and more detailed citations are unnecessary. Defendants argue that Paragraphs C(1)(a) and (b) never applied to notices for denials of prior authorization of prescription drugs; 42 C.F.R. § 431.210 does not require these additional pieces of information; and to require the additional items would be extraordinarily expensive and difficult to implement.

a. Identity of Prescriber and Dosage of Medication

Whether the notice requirements of Paragraphs C(1)(a) and (b) applied to notices for

denials of prior authorization of prescription drugs is a matter of debate. However, the Court need not resolve the debate as Plaintiffs have conceded that notices regarding denials of prior authorization of prescription drugs "must be treated differently from other medical services" because of the automated nature of system, the need for an immediate response, and frequent changes to the State's PDL, among other reasons. The Court agrees. As denials of prior authorization of prescription drugs must be treated differently, the Court finds that Paragraphs C(1)(a) and(b) are inapplicable. Consequently, the identity of the prescriber and the dosage of the medication do not need to be included in notices of denials of prior authorization for prescription drugs.

b. Regulations

42 C.F.R. § 431.210 requires that in its notices, the State include "(b) The reasons for the intended action; and (c) The specific regulations that support . . . the action." Defendants argue that it already provides the required reference to the specific regulations. (See Doc. No. 1356.) The Court has reviewed the sample denial notices and agrees with Defendants that they have sufficiently referenced the applicable regulations. Additional regulations may be referenced, but are not required.

c. Medical Necessity

The crux of the dispute is whether, with regard to denials due to medical necessity, § 431.210 requires Defendants to provide more specific reasons for the lack of medical necessity, or whether it permits Defendants to simply state that "this drug is not medically necessary for

you." The Court finds that minimum due process requires more specific reasons. The Supreme Court has required that notice must be "reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections." Mullane v. Cent. Hanover Bank & Trust Co., 339 U.S. 306, 314 (1950). Twenty years later, the Supreme Court added that "adequate notice" requires "detailing the reasons" for the State's action. Goldberg v. Kelly, 397 U.S. 254, 267 (1970). Notice providing specific reasons for the State's action is important because it provides the enrollee with facts sufficient to challenge the State's action "as resting on incorrect or misleading factual premises or on misapplication of rules or policies to the facts of particular cases." Id. at 268.

The Sixth Circuit has held that notices regarding broad changes in law or policy may include less specific reasons. Garrett v. Puett, 707 F.2d 930, 931-32 (1983) (holding that notices excluding mathematical calculations used in arriving at amount of benefits allowed for recipients was appropriate under 42 C.F.R. § 431.210). But even in the situation of broad changes in law or policy, the Sixth Circuit has implied that "sufficiently specific facts" to apprise the enrollee of the reasons for the action must be included in the notice. See Rosen v. Goetz, 410 F.3d 919, 931 (6th Cir. 2005) (stating that notice issued in two separate letters did contain sufficiently specific facts). The Sixth Circuit, however, has been silent regarding the specificity of the reasons in notices that involve the denial of medical services based on an individualized determination.

Another district court in this Circuit, however, is instructive about the specificity of the reasons in notices that involve the denial of medical services based on an individualized determination. See Moffitt v. Austin, 600 F. Supp. 295 (D.C. Ky 1984). In that case, the state of Kentucky issued notices informing Medicaid recipients in intermediate care facilities that they

were no longer eligible to continue receiving Medicaid benefits. Id. at 296. The notices consisted of a form letter with blanks to be completed. Id. at 297. The blank for "'The reason for this determination is'" was completed with two generic responses: "'Your care needs no longer meet the criteria for intermediate care,' or '[a]ccording to information in your medical record you no longer require the care provided in an intermediate care facility.'" Id. (citations omitted). The district court held that these reasons were not sufficiently specific to fulfill the requirements of 42 C.F.R. § 431.210 because they did not provide Medicaid recipients with adequate information to prepare a defense against the defendant's decision that care was no longer needed. Id. at 298. Furthermore, the district court held that these generic reasons were "deficient" pursuant to the more lenient "Sixth Circuit standards" specified in Garrett. Id.

In the present case, the reason provided by Defendants that a drug is not "medically necessary" is similar to the generic response that the Kentucky district court rejected in Moffitt. Defendants concede that there are numerous reasons why a prescribed drug may not be medically necessary. By stating that a medication is not "medically necessary," however, an enrollee has no idea on which of the potentially numerous reasons the Defendants' decision is based. By failing to provide the specific reasons why a drug is not medically necessary, enrollees are unable to challenge the Defendants' medical necessity determination "as resting on incorrect or misleading factual premises or on misapplication of rules or policies to the facts of particular cases." Goldberg, 397 U.S. at 268. The Court finds it particularly disturbing that the enrollee is not given specific reasons for the denial even though Defendants know the exact reasons underlying their medical necessity determination. Due process does not permit Defendants to hide the ball. The Court is well-aware of the difficulties and costs of providing

these specific reasons in the notice, and has been extremely cautious in its rulings so as to provide Defendants with sufficient flexibility in creating a meaningful, reasonable and cost-effective prior authorization system. The Court cannot, however, allow Defendants to fall below the minimum due process requirements delineated by the Supreme Court and federal regulations.

d. Notice of Appeal Regarding Emergency Supply of Prescription Drug

Finally, Plaintiffs seek to include in the notice of denial of prior authorization a statement that the refusal of a pharmacist to dispense a seventy-two-hour emergency supply of the prescribed medication can be included as an issue in the appeal. This statement is consistent with the Court's January 31, 2006 Order. (See Doc. No. 1328 at 3.) Defendants, however, have asked this Court to reconsider its position. Defendants state that reconsideration is appropriate as they have decided to include information about how to obtain an emergency seventy-two-hour supply in the pharmacy posters and in the pre-printed pharmacy notice. Defendants argue that this is a better method and time to provide to enrollees information about the seventy-two-hour supply so that it can make a "real difference." Including information about how to appeal the seventy-two-hour emergency supply in a notice of denial of prior authorization is meaningless, argue Defendants. In light of the new procedures Defendants have adopted, the Court GRANTS Defendants' request for reconsideration. The Court's decision is reflected in the fact that the reference to the seventy-two-hour emergency supply is deleted from Plaintiffs' proposal to Paragraph C(1)(e).

For these reasons, the Court APPROVES Plaintiffs' proposal of Paragraph C(1)(e), with

certain modifications, and REJECTS Defendants' proposal.

5. Paragraph C(1)(f)

f. The defendants and others acting on their behalf shall be bound by their own notices, and may not rely upon any reasons or legal authorities other than those which they include in their written notices to a TennCare beneficiary. The Bureau of TennCare or MCC, however, may remedy any defects or omissions in a notice after the filing of an appeal by issuing one corrected notice that must be received by the beneficiary prior to the issuance of a timely notice of hearing. When a corrected notice is issued, the enrollee shall not be required to file a new appeal or take additional steps to obtain a hearing on his original appeal. In the event that a beneficiary appeals an adverse action, the reviewing authority shall consider only factual reasons and legal authorities cited in the original notice, or, if that original notice has been corrected in conformity with this subparagraph, the corrected notice, to the beneficiary, except that additional evidence beneficial to the enrollee may be considered on appeal.

The 2003 Consent Decree bound Defendants to defective notices. This was to prevent Defendants from issuing a notice that denied the benefit based on one reason and then at the hearing denying the benefit for another reason. The Court found that the "practice of basing decisions on issues raised for the first time at the hearing violates the claimant's procedural rights, specifically the right to receive notice and to refute arguments presented by" the Defendants. (See Doc. No. 1282 at 99-100) (citations omitted). After the hearing in June-July

2005, however, the Court found it appropriate to modify the 2003 Consent Decree such that Defendants may now issue one corrected notice in the "early stages of an appeal." (Id. at 100.) The Court found that issuing a corrected notice in the early stages of an appeal provided enrollees with sufficient notice, and provided Defendants with some flexibility. The Court did not permit the issuance of a corrected notice at a later stage in the appeals process because of the potential of delaying the process in violation of 42 C.F.R. § 431.244(f). (Id.)

The current disagreement revolves around the definition of "early stages of an appeal." Plaintiffs seek to define "early stages of an appeal" as twenty days from the date of the filing of the appeal. Defendants seek to define "early stages of an appeal" as any time prior to the issuance of a hearing notice. The Court finds that providing a corrected notice prior to issuance of a hearing notice provides an enrollee with sufficient time to prepare a defense. Furthermore, for the reasons explained by Ms. Killingsworth, the Court finds Plaintiffs' suggestion to be impractical. Defendants' suggested timeline, while satisfying due process concerns, may run afoul of 42 C.F.R. § 431.244(f). At this time, however, there is no evidence that Defendants' proposal unreasonably delays an appeal. If that proves to be the case, Plaintiffs may make a motion to modify this Paragraph.

The Court recommends, however, that Defendants impose an earlier deadline for issuing corrected notices so as to avoid violating 42 C.F.R. § 431.244(f). Ms. Killingsworth identified three key stages at which a notice is reviewed for deficiencies: (1) at the initial review of an adverse action, (2) upon completion of the medical review, and (3) at the time the case is transferred to the Office of General Counsel for hearing preparation. The Court anticipates that in order to avoid unduly delaying the appeals process, a corrected notice is more appropriate

after the completion of the medical review. That recommendation aside, Defendants' proposal for Paragraph C(1)(f) is APPROVED, with a minor modification to make explicit that only one corrected notice may be issued, and Plaintiffs' proposal is REJECTED.

6. Paragraph C(1)(g)

g. If the MCC's reasons or legal authorities in the original notice (or in any notice that has been corrected in conformity with Paragraph C(1)(f)), do not meet the requirements of C(1)(a-e), then the MCC denial shall be overturned and the beneficiary shall receive the service or item requested subject to the exclusions contained in C(16)(h) and C(18). Nothing herein shall preclude the issuance of a new notice, but such new notice shall not cure the deficiencies of the original or corrected notice.

Defendants oppose this version of Paragraph C(1)(g), which Plaintiffs have proposed. Instead, Defendants propose that in the event a notice contains a "technical" defect (whether it has been timely corrected or not), Defendants shall maintain the authority to determine whether any such "technical" defect results in substantial prejudice to the enrollee. If substantial prejudice results from a notice containing a "technical" defect, the disputed service must automatically be provided. If there is no substantial prejudice to the enrollee, the disputed service will only be provided if the enrollee prevails on the merits of his or her appeal.

Defendants' proposal of "substantial prejudice" is an interesting one, but it is the enticing "second" bite at correcting notices that the Court did not permit Defendants to have. As the Court has already noted, Defendants have the opportunity to review a notice of adverse action

three times before a corrected notice may be issued. First, after the initial review of the notice of adverse action. Second, after completion of the medical review. Third, once the case is transferred to the Office of General Counsel. Thus, Defendants have three opportunities to correct the notice before they are bound by it. If Defendants cannot get it right by the third opportunity, then there is something grievously wrong with their system of review. The sanction of granting the disputed service was imposed to discourage precisely this type of sloppy review, and must be maintained. (See Doc. No. 1282 at 99.) Besides, Defendants' proposal violates their own oft-repeated mantra that modifications to a consent decree cannot be made without a Rufo hearing. Defendants presented no evidence at the Rufo hearing to support such a modification. The final death knoll to Defendants' proposal is that it does not define "technical." The administration of TennCare is replete with "technical" details. Defendants have not explained which of the requirements in Paragraphs C(1)(a)-(e) are "technical" and which are "substantive." In sum, Plaintiffs' proposal is APPROVED and Defendants' proposal is REJECTED.

7. Plaintiffs' Proposed New Paragraph C(2)(i)

i. When prior authorization for a prescribed medication is denied, the State or MCC must issue a notice informing the enrollee and his or her provider of the denial at the time of the denial although the medication may have already been denied (not dispensed) by a provider. This notice must be issued within 24 hours of receipt of a completed prior authorization request. If the day for issuance of the notice falls on a Sunday or holiday, notice must be issued no later than by the end of the next business day. The content of

the notice must conform to the requirements of 42 C.F.R. §§ 431.206-210 and Paragraph C(1)(e)(i), supra.

Defendants object to the inclusion of Plaintiffs' proposed Paragraph C(2)(i). Defendants argue that this "proposed revision is entirely redundant and unnecessary, and it creates an unreasonable and unrealistic timeframe for issuing denial notices in all cases." (Doc. No. 1374 at 38.) Defendants explain that they provide a response pursuant to 42 U.S.C. § 1396i-8(d)(5) by telephone or facsimile within twenty-four hours to the prescribing physician. They admit, however, that notice to the enrollee may take longer than twenty-four hours due to their PBM's mailing schedule. Defendants clarify that their PBM will soon shift to a daily mailing schedule, "but even when it is in place, there will be instances when a prior approval request comes in on a Friday afternoon and due to the Saturday mail cut-off time, the notice to the enrollee will not be mailed until Monday." (Id.) Defendants argue that not only would they incur unreasonable expense to modify their procedures, but such modification is unnecessary because their procedures comply "fully with federal law," notwithstanding the fact that enrollee notices are not issued within twenty-four hours.

Defendants have chosen the wrong forum in which to complain. They should take up their complaint with CMS. This Court has interpreted CMS' construction of 42 U.S.C. § 1396i-8(d)(5) "to require written notice to both the enrollee and the enrollee's provider within twenty-four hours of receipt of a completed prior authorization request." (Doc. No. 1282 at 64) (citing Def. Ex. 339 Att. F § II.2(B), at iii). CMS has stated that a "written notice of denial of a request for prior authorization shall be mailed . . . to the enrollee and transmitted . . . to the prescribing

physician." (Def. Ex. 339 Att. F § II.2(B), at iii.) At the conclusion of that section, CMS stated that the "State's failure to act upon a request for prior authorization within a 24-hour period after receiving a submission that complies with the State's requirements for a completed prior authorization request may be deemed a denial from which th enrollee can appeal." (Id.) The Court interprets CMS' requirement that the State act within twenty-four hours to encompass both a notice to the enrollee and a notice to the prescribing physician. Had CMS simply required the denial notice to be transmitted to the physician within twenty-four hours, they would have (or should have) made that clear. As it stands, CMS does not distinguish between the act of mailing a notice to the enrollee and the act of faxing a notice to the prescribing physician. Accordingly, Defendants' procedures for issuing enrollee notices later than twenty-four hours of receipt of a completed prior authorization request violates federal law, as interpreted by CMS. Until CMS reinterprets 42 U.S.C. § 1396i-8(d)(5), proposed paragraph C(2)(i) is mandated by federal law, as interpreted by CMS. The Court expects that Plaintiffs will not be so unreasonable to argue that the few requests that come in on a Friday afternoon and miss the Saturday mail cut-off time would constitute a violation of this provision. Plaintiffs' proposed new Paragraph C(2)(i) is APPROVED, with a minor modification to include a reference to notices to providers.

8. Plaintiffs' Proposed New Paragraph C(2)(j)

j. When a new request for prior authorization of medical services other than a prescription medication is denied, the State or MCC must issue a notice informing the enrollee of the denial at the time of the denial. This notice must be issued within the time required by state regulations (but no more than 21 days from the date of the request for

authorization) although the service may have already been denied (not dispensed) by a provider. The content of the notice must conform to the requirements of 42 C.F.R. §§ 431.206-210, as enhanced by Paragraph C(1), supra. If the denial of prior authorization is for services prescribed or ordered on an ongoing basis, the notice must conform to Paragraph C(2)(c), supra and Paragraph C(8), infra.

Defendants object that the insertion of this paragraph is redundant. The Court could not find any other paragraph in the 2003 Consent Decree that deals with the timing of the issuance of a notice for the denial of prior authorization of medical services. Defendants non-legal, non-substantive objection is OVERRULED. Plaintiffs' proposed new Paragraph C(2)(j) is APPROVED.

9. Paragraph C(3)(a)

a. If it comes to the attention of the defendants

i. prior to an appeal or in the early stages of an appeal (i.e. before the issuance of a timely notice of hearing), that a TennCare covered service will be or has been delayed, denied, reduced, suspended or terminated in violation of any of the notice requirements of this order, TennCare or the MCC may cure any such deficiencies by providing one corrected notice to a TennCare beneficiary. If the beneficiary has not yet filed an appeal, the time limit permitted for the beneficiary's response will be restarted upon issuance of the corrected notice.

ii. in the later stages of an appeal (i.e. after the issuance of a timely notice of

hearing), that a TennCare covered service will be or has been delayed, denied, reduced, suspended or terminated in violation of any of the notice requirements of this order, defendants shall immediately provide, or require their contractor to provide the TennCare covered service at issue in the quantity and for the duration prescribed, subject to the MCC's right to reduce or terminate the service in accordance with the procedures required by this order.

With regard to Paragraph C(3)(a), the Court finds that both parties' proposals are deficient. Former Paragraph C(3)(a) required automatic sanctions for defective notices. The Court permitted modification of this paragraph such that "defects in notices . . . in the early stages of an appeal may be . . . remedied [by issuing one corrected notice] without imposing the sanction of automatically granting the requested service." (Doc. No. 1328 at 8.) Defendants' proposed Paragraph C(3)(a) attempts to implement this ruling by removing the automatic sanction entirely, even if a notice continues to be defective in the later stages of an appeal. Plaintiffs' proposal, while more loyal to the Court's ruling, was confusing and inserted an unfeasible requirement that prior to, or in the early stages of, an appeal, the service be automatically granted pending the issuance of the corrected notice. Accordingly, the Court has combined and modified both parties' proposed Paragraph C(3)(a) to conform to the Court's prior rulings.

10. Plaintiffs' Proposed New Subsections (a)-(b) to Paragraph C(4)

4. Individualized Decisions Required. The defendants shall not employ, and shall not

permit others acting on their behalf to employ utilization control guidelines or other quantitative coverage limits, whether explicit or de facto, unless supported by an individualized determination of medical necessity based upon the needs of each TennCare beneficiary and his or her medical history.

Example: A BHO adopts a policy that routinely permits approval of only 5 therapy sessions for a given diagnosis, and that requires TennCare beneficiaries to appeal in order to receive a larger amount prescribed by their clinician. Upon appeal, the beneficiary is entitled to the full number of therapy sessions ordered by the clinician. State officials must prohibit the contractor from continuing to impose an arbitrary limit and must impose sanctions on a BHO for violating this provision.

Example: A TennCare beneficiary with a chronic illness is prescribed home health services 8 hours per day, 7 days per week, on an open-ended basis. The beneficiary's MCO approves the care for only 30 days, based upon an individualized determination that the beneficiary is unlikely to require care beyond that period. Because the decision is not the result of applying an arbitrary limit of general application, the action is not prohibited by this order. However, it does constitute an adverse action affecting benefits. The defendants or their contractor must treat the time limit on the authorization as a reduction or termination of the service, and must comply with all applicable terms of this order, including continuation of services pending appeal.

Plaintiffs' proposed subsections (a)-(b) unilaterally impose a "soft" drug limit (i.e., exceptions to limits may be granted based on individual determination of medical necessity), rather than "hard" limits (i.e., no exceptions to the limit are granted based on individual circumstances). Plaintiffs' proposal is based on the argument that Defendants have failed to move to a true "soft" limit that is based on a case-by-case individualized determination of medical necessity. As such, Plaintiffs contend that Defendants have failed to maintain their promise to this Court that a "soft" limit policy would be forthcoming. Defendants counter that they have sought CMS approval to create a modified "soft" limit by creating a "second" short list

of drugs that are exempted from the "hard" limit. In order to obtain drugs from this "second" short list after reaching their five-prescription-per-month drug limit, an enrollee would have to obtain a prescriber certification stating that the enrollee is at "high risk for health consequences that will be serious enough to result in hospitalization, institutionalization or death within 90 days." Furthermore, Defendants argue that their representation to the Court that they would move to a true "soft" limit based on individualized determination was premised on obtaining complete approval of their prior authorization program. As the Court granted most, but not all, their prior authorization requests, Defendants argue that they are not bound to implementing a true "soft" limit.

This has been a difficult issue throughout this litigation, and the Court is sympathetic to Plaintiffs' arguments that this "second" short list, combined with the prescriber certification, is a far cry from a true "soft" limit policy. Moreover, contrary to Defendants contentions, this Court granted all of Defendants requests regarding prior authorization of prescription drugs to the extent permitted by federal law. Defendants cannot seriously be arguing that in order to adopt "soft" limits they must be permitted to flout federal requirements regarding prior authorization. Nevertheless, the fact remains that the Court found that "[a]lthough the "hard" limit, along with the shortlist, skirts the boundaries of 42 U.S.C. § 1396a(a)(19) and 42 C.F.R. § 440.230," it does not deny "meaningful access or severely curtail[ ] access to medically necessary prescription drugs for most TennCare enrollees." (Doc. No. 1282 at 55-62.) Furthermore, the Court only required evidence that the Defendants were moving towards a "soft" limit policy (which they have provided), but did not detail the contours, or set a deadline for the implementation, of such a policy. As a result, Plaintiffs' proposal is REJECTED and Defendants' proposal is

APPROVED.[5]

11. Paragraph C(6)

6. Record on review. Whenever the state defendants receive an appeal from a TennCare beneficiary regarding an adverse action affecting TennCare services, the defendants shall be responsible for obtaining from their contractor any and all records or documents pertaining to the contractor's decision to take the contested action. The defendants shall be responsible for correcting any violation of this order that is evident from a review of those records. Specifically,

i. if, during the early stages of an appeal (i.e. before the issuance of a timely notice of hearing), it appears from the contractor's records that the adverse action is based on grounds other than those cited in the notice to the TennCare beneficiary, the defendants shall require the contractor to send out a revised notice to the beneficiary citing the correct grounds for the adverse action; or

ii. if, during the later stages of an appeal (i.e. after the issuance of a timely notice of hearing), it appears from the contractor's records that the adverse action is based on grounds other than those cited in the notice, or the corrected notice issued in compliance with this Decree, to the TennCare beneficiary, the

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[5] As noted in the Court's Memorandum, in order for this Court to impose a "soft" or a higher "hard" limit policy, Plaintiffs must demonstrate that the current five-prescription-per-month limit, along with the shortlist and/or the "second" shortlist/prescriber certification, "does in fact severely curtail and/or prevent meaningful access to prescription drugs and thereby deprive most TennCare enrollees from receiving medically necessary care." (Doc. No. 1282 at 61 n.16.) Until that can be demonstrated, however, the current "hard" limit policy does not violate federal law.

defendants shall overrule the contractor and take such further corrective action as is reasonably necessary to ensure future compliance.

The Court has modified both parties' proposed Paragraph C(6) for the reasons identified in the discussion of Paragraphs C(1)(f), C(1)(g) and C(3)(a) supra.

12. Paragraph (C)(7)

7. Decisions to be supported by substantial and material evidence.

In any appeal of an adverse action affecting TennCare benefits, throughout all stages of such appeal, the defendants shall ensure that decisions are based upon substantial and material evidence. In cases involving clinical judgments, this requirement specifically means that:

a. Appeal decisions must be supported by medical evidence, and it is the defendants' responsibility to elicit from beneficiaries and their treating providers all pertinent medical records that support an appeal; and

b. Medical opinions shall be evaluated as follows:

i. Where the treating provider's opinion is consistent with the defendants' or MCCs' opinion or objective evidence, it shall be accorded controlling weight.

ii. Where the treating provider's opinion is:

(1) well-supported with clinical and laboratory findings derived from

an examination of the enrollee or enrollee's medical records, and objective evidence; or

(2) well-supported with clinical and laboratory findings derived from an examination of the enrollee or the enrollee's medical records, but not with objective evidence, the opinion shall be accorded controlling weight, even if it is inconsistent with the defendants' or MCCs' opinion or objective evidence; provided, however, that the treating provider's opinion does not significantly deviate from the defendants' or MCCs' opinion or objective evidence. If the treating provider's opinion significantly deviates from the defendants' or MCCs' opinion or objective evidence, the defendants' or MCCs may require the treating provider to further explain his or her opinion.

iii. Where the treating provider's opinion is:

(1) not well-supported with clinical and laboratory findings derived from an examination of the enrollee or the enrollee's medical records, but is well-supported by objective evidence; or

(2) not well-supported with either clinical and laboratory findings derived from an examination of the enrollee or the enrollee's medical records, or objective evidence, the opinion shall be accorded minimal weight if it is inconsistent with the defendants' or MCCs' opinion or objective evidence. The defendants or MCCs

may require the treating provider to further explain his or her opinion.

iv. In the event the defendants or MCCs require further explanation from the treating provider as described in Paragraph C(7)(b)(ii) and (iii),

(1) the treating provider's opinion shall be accorded controlling weight, if the treating provider submits an explanation or other clinical or objective evidence and the defendants or MCCs deem such additional information to be sufficient to cure the original deficiency.

(2) the treating provider's opinion shall be accorded minimal weight, if the treating provider fails to submit an explanation or other clinical or objective evidence, or the defendants or MCCs deem any additional information submitted by the treating provider to be insufficient to cure the original deficiency.

v. Objective evidence may include the standard treatment for specific medical conditions or the use of specific health technologies, including evidence-based treatment guidelines and technology assessments, and the results of well-supported clinical trials and studies, recommendations from other health care providers, clinical guidelines, standards or recommendations from respected medical organizations or governmental health agencies, analyses from independent health technology assessment organizations, and policies of other health plans. In considering whether

the treating provider's opinion is well-supported by objective evidence, as described in Paragraph C(7)(b)(ii)-(iii), or whether any objective evidence submitted to cure the original deficiency is sufficient, as described in Paragraph C(7)(b)(iv), the defendants or MCCs shall consider the validity and reliability of the objective evidence (including any objective evidence upon which the defendants or MCCs rely) in accordance with the medical necessity rules enacted by the defendants.

vi. *Opinions from treating providers are valued because they are the medical professionals most able to provide a detailed, longitudinal picture of the enrollee's medical condition(s) and may bring a unique perspective to the medical evidence that cannot be obtained from objective evidence alone, or from reports of individual examinations, such as consultative examinations or brief hospitalizations.*

vii. *The notice of adverse action shall include a statement of reasons for the weight given to the treating provider, including, but not limited to, the supportability of the opinion with clinical and laboratory findings and objective evidence, and the consistency of the opinion with the medical record as a whole, including any objective evidence upon which the defendants or MCCs rely. If the defendants or MCCs invoke objective evidence as the basis for the adverse action, they shall describe with specificity the objective evidence supporting their judgment and how it*

applies to the unique medical condition of the individual beneficiary.

c. Reliance upon objective evidence, as defined in Paragraph C(7)(b)(v), without consideration of the individual enrollee's medical history is prohibited and cannot be relied upon to support an adverse action affecting TennCare services.

After finding that neither party appropriately modified Paragraph C(7)(b), the Court ordered the parties to adopt its revision to Paragraph C(7)(b). Predictably, the parties have filed motions to clarify and/or amend the Court's revision to Paragraph C(7)(b).

Defendants assert that "[w]hile it appears to be feasible for the State to adapt its policies and procedures to comply with the Court's new order in the context of medical service claims, it would be highly impractical and expensive for the State to do so in the context of pharmaceutical claims." (Doc. No. 1358 at 1-2.) Defendants request a clarification that Paragraph C(7)(b) does not apply to <u>any aspect</u> of pharmaceutical appeals, including the prior authorization process for pharmacy claims or the content of pharmacy notices. (<u>Id.</u>)

Plaintiffs readily concede that, "due to the volume of claims for pharmacy benefits and the short time for prior authorization, it is not feasible for the PBM to obtain actual medical records and, in some instances, to converse with the prescribing clinician." (Doc. No. 1370 at 18) (emphasis added). Plaintiffs, however, argue that <u>once the beneficiary appeals</u> the denial of prior authorization for a prescribed medication, and TennCare affirms such denial, the process of affirming the denial and the notice issued thereafter must comport with Paragraph C(7).

Defendants counter that Plaintiffs' bifurcation of the prior authorization process is

misleading because the Defendants are not required to and do not issue reconsideration notices for pharmacy appeals. Defendants explain that once the PBM issues a denial of prior authorization, a notice of adverse action is sent to the enrollee and provider. Subsequently, the State conducts two individualized determinations of medical necessity in accordance with the medical necessity rules. If, after these determinations, the initial denial of prior authorization is upheld, the file is transferred to the Office of General Counsel, and a notice will be issued to the enrollee.

It appears to the Court that Paragraph C(7) previously applied to pharmaceutical notices and appeals. Nevertheless, the Court finds that Paragraph C(7), as modified by this Court's recent rulings, should not apply to pharmaceutical notices and appeals. There are numerous reasons for the Court's decision. First, the Court notes that both parties agree that pharmaceutical notices and appeals are different from medical services notices and appeals. Second, both the prior authorization system and Paragraph C(7)(b) have been modified significantly. Third, Paragraph C(1)(e), as modified in this Memorandum Order, provides a beneficiary with the necessary due process protections required to adequately prepare for a hearing at the outset. Fourth, Defendants have agreed to provide further information, just not in the format of Paragraph C(7), to enrollees when the case is transferred to the Office of General Counsel. This information will consist of the medical necessity analysis conducted by the State after the initial denial of prior authorization by the PBM, and before the case is transferred to the Office of General Counsel. Thus, Defendants' motion for clarification is GRANTED in its entirety.

Further, the Court GRANTS Plaintiffs' motion for clarification, but DENIES its motion

for amendment. Plaintiffs seek clarification of subsection C(7)(b)(iv), which states:

> the treating provider's opinion shall be accorded controlling weight, if the treating provider submits an explanation or other clinical or objective evidence and the defendants or MCCs deem such additional information to be sufficient to cure the original deficiency.

Plaintiffs' oppose the underlined language on the basis that it

> could be construed to mean that the defendants or MCCs enjoy unfettered discretion in determining the adequacy of the treating physician's explanation or of the other clinical or objective evidence that he submits. Such an interpretation could mean that the State's treatment of the physician's opinion or other evidence submitted by the treating physician would not be reviewable by an ALJ or the Commissioner's designee.

(Doc. No. 1359 at 2.) The Court certainly did not intend that to be the case. Although an amendment of the language is unnecessary, a clarification is in order. At the prior authorization stage only the State or the MCCs can make the determination of whether additional evidence submitted by a provider in support of a request for prior authorization cures any deficiencies in the original request. If prior authorization is denied and an enrollee appeals, the issue on appeal will be whether the evidence submitted by the treating provider (all of the evidence) supports the medical necessity of the ordered service. Ultimately, an ALJ or the Commissioner's Designee will weigh all of the evidence -- including evidence submitted by (a) the provider initially, (b) the provider later upon request by the Defendants or the MCCs, (c) the Defendants and MCCs, as well as (d) any other evidence that is in the record – to render a decision on whether a requested service is medically necessary.

Second, the Court sua sponte modified subsection C(7)(c) to remove the reference to insurance industry guidelines or utilization control criteria of general application. The Court felt, and still feels, that such language is redundant due to the use of the all-encompassing term

"objective evidence." If it was not clear before, let it be clear now, "insurance industry guidelines or utilization control criteria of general application" are included in the term "objective evidence." The Court declines to explicitly reference these terms in subsection C(7)(c) because to do so would imply that all other types of "objective evidence" are excluded.

In sum, Paragraph C(7) is APPROVED, with the clarifications listed above.

13. Paragraph C(10)(b)

b. Refusing to provide an appeal because the beneficiary lacks an order or prescription from a provider supporting the appeal; provided however, that the State may create an administrative grievance or other informal process to address appeals by enrollees without an order or prescription, including but not limited to network access requests, and may require an enrollee to exhaust that administrative grievance or informal process, during which time the appeal timelines will be tolled, before the enrollee's appeal can go forward. If Defendants elect to create such an administrative grievance or informal process, it must be completed with reasonable promptness or the time limitations in Paragraph C(16)(b), (f) and (g) shall restart.

Plaintiffs' propose to include a specific definition of "reasonable promptness." For the reasons stated in the discussion of Paragraph B(6)(c) supra, this proposal is rejected.

Plaintiffs' proposal also seeks to clarify how the time limitations in Paragraph C(16) will be tolled. Plaintiffs suggest that the time limitations will "resume." For example, if the State informs the enrollee that exhaustion of an administrative grievance is required ten days after an

appeal is filed, once the administrative grievance is exhausted or the time for the grievance has expired, the time for processing the appeal resumes as of the eleventh day.

Defendants do not appear to challenge the fact that the appeal will resume, in this particular example, on the eleventh day. Rather, Defendants argue that the term "resume" implies that without further action from the enrollee, once the time for the administrative grievance process has been exhausted, the appeal will automatically resume on the eleventh day. Defendants disagree with this automatic resumption and assert that in order for the appeal to resume on the eleventh day, the enrollee must contact TennCare to inform the State that the enrollee wants the appeal to continue. Without the contact from the enrollee, Defendants argue, the State will have no way of knowing whether the enrollee was satisfied with the administrative process and no longer wishes to continue with the appeal.

The Court agrees with Defendants. In order for the appeals process to continue on, in our example, the eleventh day, the enrollee must contact TennCare to inform the State that the enrollee wishes to continue with the appeal. To rule otherwise would be to defeat the purpose of the administrative process. Defendants must clearly communicate two things to the enrollees in order to operate the administrative process in this manner: (1) how long the administrative grievance or informal process will take (i.e., when can an enrollee challenge the process as not being "reasonably prompt" and therefore request a resumption of his or her appeal); and (2) that the enrollee must contact TennCare to restart the appeal.

For these reasons, Plaintiffs' proposed Paragraph C(10)(b) is REJECTED and Defendants' proposed Paragraph C(10)(b) is APPROVED, with a minor modification to remove the erroneous cross-reference to Paragraph C(9) and include the correct cross-reference to

Paragraphs C(16)(b), (f) and (g).

14. Paragraph C(10)(g)

g. Refusing to provide an appeal because the class member seeks to contest or change his assignment to a particular MCO or BHO.

For the reasons outlined in the discussion of Paragraph B(6)(c) supra, Defendants' proposal to create an administrative grievance or other informal process to address MCO change requests outside of open enrollment periods is REJECTED. Thus, Paragraph C(10)(g) is not modified.

15. Plaintiffs' Proposed New Paragraph C(10)(l)

l. Refusing to provide an appeal because a provider:

i. Fails or refuses to request prior authorization;

ii. Refuses to render services because an enrollee has reached a benefit limit; or,

iii. Refuses to render services because an enrollee fails to make a co-payment.

Provided, however, that the State may create an administrative grievance or other informal process to address appeals lacking a request for prior authorization pursuant to Paragraph C(14).

Defendants assert that the insertion of this paragraph is redundant. The Court, however, could not find any other paragraph in the Consent Decree that deals with this issue. Defendants'

non-legal, non-substantive objection is OVERRULED. Plaintiffs' proposed new Paragraph C(2)(j) is APPROVED, with a minor modification to cross-reference Paragraph C(14) and to remove the cross-reference to Paragraph B(18). The cross-reference to Paragraph B(18) regarding valid factual disputes is unnecessary because it is implicit that all references to "appeals" in the Consent Decree are governed by Paragraph B(18).

16. Paragraph C(13)

13. *When the beneficiary prevails. Defendants are permitted to seek final agency review by the TennCare Commissioner or his designee(s) in any appeal in which the enrollee prevails by decision of an administrative law judge (ALJ) who is not an employee or official of the Department of Finance and Administration or Bureau of TennCare. Provided, however, that if the enrollee prevails at any stage of the appeal process and defendants seek final agency review, defendants may not await the conclusion of this review before providing prompt corrective action as defined by Paragraph C(16)(c), infra, and in accordance with 42 C.F.R. § 431.246. Further, an ALJ's decision in an enrollee's appeal shall not be deemed precedent for future appeals. The defendants may also enact emergency rules or public necessity rules in accordance with the state Administrative Procedures Act.*

Both parties' proposals regarding Paragraph C(13) ignore the Court's previous Orders. On the one hand, Plaintiffs attempt to include a reference to the Tennessee Uniform Administrative Procedures Act, which this Court has already found conflicts with federal law.

(See Doc. No. 1328 at 5-7.) Thus, Plaintiffs' proposed reference to the Tennessee Uniform Administrative Procedures Act is REJECTED.

On the other hand, Defendants argue that they should not be limited to seeking final agency review of only those appeals decided by an ALJ who is not an employee or official of the Department of Finance and Administration or Bureau of TennCare. Defendants urge the Court to "reject this language because it unnecessarily and impermissibly intrudes upon the State's internal assignment of functions without any basis in federal law." (Doc. No. 1374 at 42.) Defendants should reconsider their umbrage at Plaintiffs' proposal after re-reading pages 90-92 of this Court's Memorandum (Doc. No. 1282). Upon this re-reading, Defendants will find that Plaintiffs' proposal simply tracks this Court's ruling, which permitted a modification of Paragraph C(13) based on CMS' recent clarification of federal law.

Specifically, the Court stated: "Federal law, pursuant to CMS' recent clarification, states that when hearing officers are not officials of the single state agency, they cannot issue decisions, policies, or similar actions that are binding on the single state agency. (Def. Ex. 353); see also 42 C.F.R. § 431.10(e)(3)." (Doc. No. 1282 at 91) (emphasis added). The Court also noted that section 431.10(e)(3) provides:

> If other State or local agencies or offices perform services for the Medicaid agency, they must not have the authority to change or disapprove any administrative decision of that agency, or otherwise substitute their judgment for that of the Medicaid agency with respect to the application of policies, rules, and regulations issued by the Medicaid agency.

(Id.) Based on CMS' interpretation of federal law the Court permitted the State to "appeal a medical appeal decision rendered at any stage of the process in favor of the enrollee when such decision is made by a hearing officer that is not an official of TennCare. Paragraph C(13) is still

applicable, however, when a decision in favor of the enrollee is made by an official of TennCare." (Id.) (emphasis added). Should Defendants want to change this provision, they should point this Court to the relevant statute or regulation that supports their position. Otherwise, their complaints are best presented to CMS or Congress.

In conclusion, Plaintiffs' proposal is APPROVED, with certain modifications and Defendants' proposal is REJECTED.

17. Paragraph C(14)(b)-(d)

b. When prior authorization is required and the drug is otherwise covered (e.g., drug is not a DESI, LTE, or IRS drug, drug is not in a non-covered TennCare therapeutic class, drug is not an over-the-counter medication, drug is not in excess of benefit limits), and when a provider with prescribing authority, as defined in paragraph B (17), prescribes a medication for a beneficiary, and the prescription is presented at a pharmacy that participates in the TennCare program, the beneficiary's rights are as follows:

i. To receive the drug as prescribed, if the drug is on the TennCare PDL and prior authorization is either unnecessary or, if required, has been obtained; or

ii. To receive the drug as prescribed, if the prescribing provider has obtained prior authorization or established the medical necessity of the medication; or

iii. To receive an alternative medication on the TennCare PDL, if the pharmacist consults the prescribing provider when the beneficiary presents the prescription to be filled, and the provider prescribes the substituted drug, or

iv. To receive notice that the prescribed drug requires prior authorization, which has

not been obtained. This written notice shall advise the enrollee of how he and his provider can seek prior authorization. Subject only to the emergency supply provisions in paragraph 14(c) below, no drug shall be dispensed for which prior authorization is required but has not been obtained.

c. When an enrollee presents a prescription for which prior authorization is required but has not been obtained and in the judgment of the dispensing pharmacist there exists an immediate threat of severe adverse consequences to the enrollee if the drug as prescribed is not dispensed, the dispensing pharmacist shall dispense an emergency 72-hour supply of the prescribed medication. In no event, however, shall an enrollee be provided an emergency 72-hour supply if the prescription is denied for one of the following reasons:

i. The medication is classified by the FDA as less than effective (i.e., a DESI, LTE, or IRS drug); or

ii. The medication is a a non-covered drug for adults (e.g., 1) drugs in a non-covered TennCare therapeutic class – e.g., appetite suppressants, drugs to treat infertility, etc; 2) a drug in excess of benefit limits; or 3) an over-the-counter drug); or

iii. Use of medication has been determined, in accordance with subsection (C)(18) of this order, to be medically contraindicated because of the patient's medical condition or possible adverse drug interaction.

d. In some circumstances it is not feasible for the pharmacist to dispense an emergency 72-

hour supply, because the drug is packaged by the manufacturer to be sold as the original unit or because the usual and customary pharmacy practice would be to dispense the drug in the original packaging. Examples would include, but not limited to, inhalers, eye drops, ear drops, injections, topicals (creams, ointments, sprays), and drugs packaged in special dispensers (birth control pills; steroid dose packs), and drugs that require reconstitution before dispensing (antibiotic powder for oral suspension). When coverage of an emergency 72-hour supply of a prescription would otherwise be required and when, as described above, it is not feasible for the pharmacist to dispense an emergency 72-hour supply, it shall be the responsibility of TennCare to provide coverage for either the emergency 72-hour supply or the usual dispensing amount, whichever is greater.

The parties presented very different proposals regarding Paragraph C(14)(b)-(d). Plaintiffs' proposal does not sufficiently consider the Court's previous ruling permitting significant modifications to the prior authorization regime. (See Doc. No. 1282 at 45-52.) Accordingly, Plaintiffs' proposal is REJECTED and Defendants' proposal is APPROVED.[6]

[6] There is one issue that merits brief discussion. Plaintiffs' proposal included a requirement that an emergency supply be dispensed if a prescribing physician or clinician (as opposed to a pharmacist) has indicated that one is needed. Defendants objected to this inclusion. Defendants' objection is baseless, as the Court has previously noted that "the State's proposal does not preclude the physician . . . from noting on the prescription that in the event prior authorization is required [but has not been obtained], an emergency situation exists [such that a seventy-two-hour emergency supply is necessary]." (Doc. No. 1282 at 50.) Nevertheless, the Court declines to adopt Plaintiffs' proposal, which makes this situation explicit. In its Memorandum, the Court believed, and still believes, that pharmacists are not going to ignore a physician's prescription at the risk of harming an enrollee's health. As a result, an explicit reference to this situation is unnecessary.

18. Paragraph C(14)(g)

g. An enrollee may file an appeal where no prior authorization has been sought for a drug requiring such authorization (and therefore no prior authorization request has been denied). The state may establish an administrative grievance or informal process to address appeals by enrollees with a prescription that lacks the requisite prior authorization. The state may require an enrollee to exhaust this administrative grievance or informal process before the enrollee is notified of his right to appeal and before the enrollee may appeal, provided however, that the state completes the administrative process with reasonable promptness. The administrative process may include, but is not limited to:

i. Performing the prior authorization analysis prior to processing the appeal, consistent with subparagraph (ii) of the Revised Order (Doc. 1256);

ii. Requiring the enrollee to request his or her treating clinician to obtain prior authorization;

iii. Assisting the enrollee in obtaining access to a clinician who can obtain the required prior authorization in the event an enrollee is unable to reach his or her treating physician or does not have access to a clinician; or

iv. Assisting the enrollee in any other manner to obtain the required prior authorization.

The Court APPROVES Plaintiffs' proposed modification, except for the definition of "reasonable promptness," which is excluded for the same reasons outlined in the discussion of

Paragraph B(6)(c) supra. Defendants object to the inclusion of subparagraphs (i)-(iv), as creating a rigid administrative process. Subparagraphs (i)-(iv) are simply listed as examples of what the administrative process may include. Defendants are not bound by them and can modify the administrative process without seeking approval from this Court as long as such modification conforms with federal law.

19. Paragraph C(16)(a-b)

a. Subject to the provisions of subparagraphs (h) and (i), below, the failure of an MCC to act upon a request for prior approval within the time established by state regulations or 21 days, whichever is greater, shall result in automatic authorization of the requested service.

b. Managed care contractors shall make good faith efforts to complete reconsideration of beneficiary appeals within 14 days of notification by the defendants in the case of a standard appeal, or within 5 days in the case of expedited appeals involving time-sensitive care. However, in the case of expedited appeals, when it is necessary for the MCC to have additional time to obtain medical records, the MCC may have up to 14 days from notification by defendants to complete their reconsideration review and the timeline for processing an expedited appeal may be increased to a total of 45 days. If a MCC fails to complete reconsideration of an appeal within the time required under this subparagraph, defendants may remedy the missed deadline, but in no event can a remedy of a missed deadline cause an expedited appeal to take longer than 45 days, as specified by this subparagraph, or a standard appeal to take longer than 90 days, as specified by

42 C.F.R. § 431.244(f). If a missed deadline causes a violation of the 45 or 90 day deadline, whichever is applicable, the defendants shall immediately resolve the appeal in favor of the beneficiary subject to the provisions of subparagraphs (g), (h) and (i) infra.

Paragraph C(16)(a) previously provided that a MCC's failure to act upon a request for prior approval within twenty-one days resulted in the automatic authorization of the requested service. The Court previously held that Paragraph C(16)(a) has not been modified. (Doc. No. 1328 at 9.) In doing so, the Court noted that there was an inconsistency between Paragraph C(16)(a) and state regulations. The former gave MCCs twenty-one days within which to act upon a request for prior approval, whereas the latter reduced that time to fourteen days. Plaintiffs now propose that the sanction of immediately authorizing the requested service should be imposed if a MCC fails to act within fourteen days. As Paragraph C(16)(a) has not been modified, however, this cannot be so. Thus, the Court makes a reference to the state regulations, but provides that the sanction is only imposed if MCCs fail to act within twenty-one days.

Next, Plaintiffs and Defendants differ as to the time required to complete an expedited appeal in the event that a MCC requires additional time to obtain medical records to conduct the reconsideration review. Plaintiffs propose that the time be extended from thirty-one to forty days, whereas Defendants propose forty-five days. The Court finds that Defendants' proposal is appropriate for two reasons. First, the time required to complete all expedited appeals remains thirty-one days. The only time such deadline is extended to forty-five days is when a MCC requires additional time to obtain medical records to conduct the reconsideration. The Court explicitly permitted an extension of the thirty-one day deadline in this specific situation. (Doc.

No. 1282 at 95.) Second, the Court previously stated that a timeline that greatly exceeded thirty-one days may not comply with federal regulations. (Id. at 95-96.) Plaintiffs have not explained how a forty-five day deadline violates federal regulations, while a forty-day deadline is appropriate.

Finally, Defendants' proposal appropriately includes a reference to the fact that in the context of appeals, a MCC's failure to complete the reconsideration of an appeal within the time required may be remedied without granting the service. This is in compliance with this Court's previous rulings. (See Doc. Nos. 1282 at 94-96, Doc. Nos. 1328 at 10-11.) The Court, however, explained that remedying a missed deadline could not violate 42 C.F.R. § 431.244(f), which provides that a standard appeal must be resolved within ninety days and an expedited appeal must be resolved within three days after the agency receives the file. (Doc. No. 1282 at 94.) The Consent Decree has modified 42 C.F.R. § 431.244(f) regarding expedited appeals. (Id.) Defendants' proposal provides that the appeal shall be resolved in favor of the beneficiary if a missed deadline causes a violation of 42 C.F.R. § 431.244(f). This, however, appears to exclude expedited appeals because the Consent Decree's expedited appeal regime is different from the federal government's expedited appeal regime in 42 C.F.R. § 431.244(f). Thus, the Court has modified Defendants' proposal to explicitly reference both standard and expedited appeals.

Plaintiffs object to Defendants' proposal arguing that it does not provide any effective sanction against the MCC, and permits the MCC to routinely fail to meet deadlines. (See Doc. No. 1328 at 11.) Defendants, however, have created a system of liquidated damages, which they suggest will provide a sufficient punishment for MCCs such that the MCCs' failure to meet deadlines will be the exception, not the routine. The Court finds that such a sanction is

appropriate and consistent with this Court's recommendation to the parties to discuss alternative incentives or penalties that could be imposed to reduce the number of deadlines missed. (Id.)

Accordingly, Plaintiffs' proposal regarding Paragraph C(16)(a) is APPROVED, with the modification identified above, and Defendants' proposal regarding Paragraph C(16)(b) is APPROVED, with the modifications identified above.

20. Paragraph C(16)(f)

f. The defendants shall ensure that all standard appeals, including, if not previously resolved in favor of the enrollee, a hearing with an ALJ, are resolved within 90 calendar days of the defendants' receipt of the enrollee's request for an appeal. In cases involving time-sensitive care, as defined in Paragraph B(16), the defendants shall ensure that expedited appeals, including, if not previously resolved in favor of an enrollee, a hearing before an ALJ, are resolved within 31 calendar days (extended to 45 calendar days when necessary to allow sufficient time to obtain the enrollee's medical records) of the defendants' receipt of the request for an appeal. Calculation of the deadline may be adjusted so that the defendants are not charged with any delays attributable to the beneficiary. However, no delay may be attributed to a beneficiary's request for a continuance of the hearing, if she received less than three week's notice of the hearing, in the case of a standard appeal, or less than one week's notice, in the case of an expedited appeal. A beneficiary may only be charged with the amount of delay occasioned by her acts or omissions, and any other delays shall be deemed to be the responsibility of the defendants.

Example: A beneficiary receives one week's notice of his expedited appeal hearing but requests an additional week to obtain counsel and prepare his case. The hearing is continued a month. Only one week of the delay is attributable to the beneficiary.

Plaintiffs' proposal includes a cross-reference to Paragraph B(16)'s definition of "time-sensitive" care, with which this Court agrees. Defendants propose that expedited appeals be resolved within thirty-one days, except when a MCC requires additional time to obtain medical records, at which time the expedited appeal shall be resolved within forty-five days. For the reasons outlined in Paragraph C(16)(a-b) supra, the Court finds Defendants' proposal regarding the deadline of expedited appeals to be reasonable. As such, the Court has taken suggestions from both parties, and APPROVES Paragraph C(16)(f), as written above.

21. Paragraph C(16)(g)

g. Failure to meet the 90 day or 31 day (extended to 45 calendar days when necessary to allow sufficient time to obtain the enrollee's medical records) deadline, as applicable, shall result in automatic TennCare coverage of the services at issue pending a decision by the ALJ and/or review by the TennCare Commissioner or his designee that overturns or modifies the ALJ's decision, subject to the provisions of section (C)(18) relating to medical contraindication and subject to the provisions of subparagraphs (h) and (i) below. This conditional authorization will neither moot the pending appeal nor be evidence of the enrollee's satisfaction of the criteria for disposing of the case, but is simply a compliance mechanism for disposing of appeals within the time frames established by this order. In the event that the appeal is ultimately decided against the

beneficiary, she shall not be liable for the cost of services provided past the deadline for resolution of the appeal.

The Court APPROVES Plaintiffs' proposal, as it properly includes a reference to expedited appeals. However, consistent with the changes in Paragraphs C(16)(a)-(b) and C(16)(f), the Court modified Plaintiffs' proposal to clarify that an expedited appeal in which additional time is required to obtain the enrollee's medical records may take up to forty-five days.

22. Paragraph C(17)(b), (d)

b. Requiring enrollees who request a hearing before an administrative law judge to waive the 90 day or 31 day (unless extended to 45 days when necessary to obtain enrollee's medical records) deadline, as applicable, altogether as a condition of obtaining an opportunity to prepare for the hearing;

d. Failing to inform enrollees of their right to receive disputed services, as provided in this order pending a decision on their appeal, when such appeals have not been decided by the 90th day following receipt of the request for a standard appeal, or 31st day (extended to the 45th day when necessary to obtain enrollee's medical records), in the case of an expedited appeal.

For the reasons already identified in the discussion of Paragraphs C(16)(a-b) and C(16),

the Court APPROVES Defendants' proposal.

23. Plaintiffs' Proposed Restoration of Paragraph C(20)(a)

a. Within seven days of the entry of this order, the defendant state officials shall issue appropriate notices to their contractors, to TennCare providers within thirty days, and to TennCare beneficiaries within sixty days informing them of the rights and responsibilities established by this order.

NOTE: Subparagraphs (a-b) of State's proposed Paragraph C(20) should be relettered (b-c).

Defendants seek to omit Paragraph C(20)(a). Defendants argue that this is obsolete language and is no longer applicable, as the bulk of the education effort contemplated by Plaintiffs' proposal has already been conducted. Moreover, Defendants argue that Paragraph C(20)(a) is not realistic (for example, notices cannot be issued to contractors within seven days). Notwithstanding their objection, Defendants have not explained what specific procedures and policies they have implemented to educate contractors, providers and beneficiaries. Thus, the Court has no idea when Defendants have sent notices (and in what form) to contractors and providers. Further, Defendants' response implies that beneficiaries have not been informed of any of the changes and will only be informed when the annual notices are sent out. The Court might agree that the annual notice is sufficient if that annual notice is to be sent out relatively soon. If the notice is to be sent out in December, however, that may be too late. The Court agrees with Plaintiffs that the Decree must include some guidelines of how the contractors, providers and beneficiaries will be informed of the changes in the Decree – otherwise this effort

to modify the Decree is of no use. Nevertheless, the Court also finds Defendants must be allowed some flexibility in creating appropriate policies and procedures to educate the public.

As a result, the Court RESERVES ruling on this issue. The Court further ORDERS the Plaintiffs and Defendants to discuss a reasonable modification to this Paragraph. "Reasonable" in this context means that the Plaintiffs must consider the efforts that Defendants have already expended, and Defendants must consider Plaintiffs' suggestions. The Court ORDERS the parties to submit a joint proposal within ten days of the entry of this Order. If the parties are unable to agree on a proposal -- which this Court sadly recognizes will be the case -- both parties may submit their alternative proposals within ten days of the entry of this Order. In the event the parties are unable to agree, and Defendants submit a vague statement that they intend to educate the contractors, providers and beneficiaries, they must submit a detailed affidavit outlining the efforts they have already expended and those they intend to take. Specifically, the Court is interested in hearing about the timeline under which Defendants are operating.

24. Plaintiffs' Proposed Restoration of Section E

E. Attorneys' Fees

Pursuant to the Court's Memorandum Order (Doc. No. 1342), the plaintiffs are partially prevailing parties for purposes of their entitlement to an award of attorneys' fees under 42 U.S.C. § 1988 for legal services rendered by their counsel in connection with monitoring, implementation and enforcement of the 2003 Consent Decree, and proceedings related to the defendants' motion to modify and/or clarify the 2003 Consent Decree (Doc. No. 908).

Defendants object to this provision on the basis that Plaintiffs' entitlement to attorneys' fees is being litigated separately and will be resolved separately and on a different time schedule. Defendants, however, ignore the fact that this Court has already ruled that Plaintiffs are partially prevailing parties and are entitled to legal fees related to the monitoring, implementation and enforcement of the 2003 Consent Decree, as well as proceedings related to modifying the 2003 Consent Decree. The only remaining litigation in this Court is the amount due to Plaintiffs. Such litigation does not have an impact on the insertion of this Section in the Decree. Only in the event Defendants appeal this Court's ruling to the Sixth Circuit, and the Sixth Circuit reverses this Court's decision, may Section E be removed. But that time has not arrived. Furthermore, Defendants' objections to this Paragraph are tardy -- they should have included them in their motion to modify the 2003 Consent Decree, but failed to do so. As a result, Plaintiffs' Proposed Restoration of Section E is APPROVED.

25. Plaintiffs' Proposed Restoration of Section F

F. Effective Date

Except as otherwise explicitly provided herein, the provisions of this order which have not already taken effect under the terms of previous orders shall take effect within 30 days of entry of this order.

NOTE: Defendants' proposed sections E and F should be re-lettered G. and H.

On the one hand, Defendants oppose the inclusion of this provision because it is confusing. This non-legal, non-substantive objection is OVERRULED. On the other hand,

Plaintiffs attempt to include specific timing requirements as to when the Defendants should amend or revise regulations and notice templates to comply with the Decree. These are new requirements that were not included in the 2003 Consent Decree. Unless this addition is agreed upon by the Defendants, or Plaintiffs make a motion to modify the Decree and a hearing is held to determine if modification is appropriate, the Court declines to impose it. In sum, Plaintiffs' proposal is partially APPROVED.

26. Paragraphs C(2)(g), C(8)(b), C(9)(h), C(12)(f)

Defendants have included the following phrase in the first sentence of numerous paragraphs: "Notwithstanding any provision in this Decree or any other order of the Court to the contrary, . . ." Defendants' rationale for the addition of this phrase is that without it, "potentially contradictory provisions of the Decree or other orders issued over the quarter century history of this case could be cited to foreclose implementation of reforms the Court clearly approved." (Doc. No. 1374 at 37.) Defendants, however, cite to no provisions in the Decree or other orders of the Court that are contrary to the current modifications or that would foreclose implementation of the current modifications. The Court finds this added verbiage to be confusing and entirely unnecessary. Thus, this phrase must be removed where ever it appears in the Consent Decree, including Paragraphs C(2)(g), C(8)(b), C(9)(h), C(12)(f).[7]

27. Definition of "Time-Sensitive Care" For Expedited Appeals

[7] Plaintiffs also proposed additional minor modifications to Paragraphs C(8)(b) and C(9)(h). These modifications are REJECTED.

Plaintiffs contend that Defendants have ignored the Court's refusal to modify the definition of "time-sensitive care" as embodied in Paragraph B(16). While Defendants have not changed Paragraph B(16), they have enacted Public Necessity Rules defining "time-sensitive care," and have revised the medical appeal forms.

a. Time-Sensitive Care Rule

Plaintiffs argue that the Public Necessity Rules re-define "time-sensitive care" in contradiction of Paragraph B(16).

Paragraph B(16) states:

> Time-sensitive care is care which requires a prompt medical response in light of the beneficiary's condition and the urgency of her need, as defined by a prudent lay person; provided, however, that a case may be treated as non-time sensitive upon written certification of the beneficiary's treating physician.

Public Necessity Rule 1200-13-13-.01(113) ("Time-Sensitive Care Rule") states:

> TIME-SENSITIVE CARE shall mean (1) the TennCare Bureau has determined that the care is time-sensitive or (2) the enrollees' treating physician certifies in writing that if enrollees do not get this care within ninety (90) days:
> (a) They will be at risk of serious health problems or death,
> (b) The delay will cause serious problems with their heart, lungs, or other parts of their body, or
> (c) They will need to go to the hospital.

The Time-Sensitive Care Rule does not discuss the "prudent lay person" standard. This in and of itself is not problematic. However, as phrased, the rule implies that care can only be considered time-sensitive if (1) the TennCare Bureau so determines, or (2) the enrollee obtains the treating physician's certification. Such an implication is a direct violation of Paragraph B(16), which was not modified. Defendants, however, argue that notwithstanding the plain language of the Time-Sensitive Care Rule, Defendants' interpretation of the Rule is in

accordance with this Court's previous Orders. Thus, Defendants contend that the Rule apparently makes clear that if "the treating physician fails to respond to the request for certification, the appeal will remain expedited except in the limited circumstances of an appeal involving a short list of services that are never expedited." (Doc. No. 1374 at 27.) Furthermore, the reference to the TennCare Bureau's determination is a reference to "the list of services for which a timely filed appeal is always treated as an emergency even without a doctor's certification when an emergency appeal is requested by the enrollee." (Id.)

It is obvious that the "plain language" of the Time-Sensitive Care Rule is not plain, nor is it clear. Defendants discuss a "list of services" for which an emergency appeal can never be filed. While such a list is not contrary to the Consent Decree, (see Doc. No. 1282 at 97), the Time-Sensitive Care Rule does not identify any list. Nor does the fact that time-sensitive care is granted because the "TennCare Bureau has determined that care is time-sensitive" illuminate the fact that certain services are always treated as emergencies, even without a doctor's certification. Finally, Defendants state that they interpret the Rule in such a manner that even if the physician fails to respond to a certification request, the appeal will remain expedited except for the "list of services" that are never expedited. The Rule, however, fails to explain, let alone mention, this interpretation. The Time-Sensitive Care Rule must be revised to explicitly reflect Defendants' interpretation and/or application of time-sensitive care, which appears to be consistent with Paragraph B(16).

b. Medical Appeal Form

Plaintiffs also object to the modification of the medical appeal form, which states in

pertinent part:

> 4. **Do you and your doctor think you <u>have an emergency</u>?**
> Usually, your appeal is decided within **90 days** after you file it. BUT, **if you have an emergency,** you may not be able to wait 90 days. **An emergency means if you <u>don't</u> get the care or medicine sooner than 90 days:**
> - You will be at risk of serious health problems OR you may die.
> - OR, it will cause serious problems with your heart, lungs, or other parts of your body.
> - OR, you will need to go into the hospital
>
> **Do you and your doctor think that you have an emergency?** If so, you can ask TennCare for an emergency appeal. **Have your doctor sign below** saying that this appeal is an emergency. What if your doctor doesn't sign below but you ask for an emergency appeal? Then, we'll ask your doctor to tell us in writing if your appeal is an emergency. What if your doctor says your appeal isn't an emergency? Then, we'll decide your appeal within 90 days.

(Doc. No. 1361, App'x F.) This text is followed by a certification box for the doctor to sign.

Plaintiffs argue that by listing types of emergency situations, the form does not contemplate other situations where care may be legitimately needed within ninety days. The Court disagrees. The Court specifically permitted Defendants to modify the medical appeal form to "include in its instructions . . . examples of time-sensitive care and non-time-sensitive care to further guide enrollees." (Doc. No. 1282 at 97.) Moreover, while Plaintiffs assert that these examples limit "other situations" that may be time-sensitive, the Court finds that the example -- "You will be at risk of serious health problems" -- is a catch-all example that sufficiently covers any type of emergency situation in which the enrollee feels that he or she requires "prompt medical" care.

Finally, Plaintiffs argue that the phrase "Do you and <u>your doctor</u> think you have an emergency?" along with the physician certification box implies that an <u>enrollee</u> must obtain the physician's certification in violation of this Court's Memorandum. (Doc. No. 1282 at 98-99.)

The Court agrees that the form is slightly misleading. The phrasing of the question must be revised to inform the enrollee that he or she may obtain a physician certification, but he or she is not required to do so. For example, Defendants may revise the form to read:

> **Do YOU think you have an emergency**? If so, you can ask TennCare for an emergency appeal. **We'll ask your doctor** to tell us in writing if your appeal is an emergency. **BUT** your appeal will go **faster** if you have your doctor sign below saying that this appeal is an emergency. What if **you cannot** ask your doctor? Don't worry, **we'll still** ask your doctor.

Obviously, this is just a suggestion, as the Court is not an expert in sixth-grade English or in drafting notices to TennCare enrollees.

As the Court's example makes clear, however, contrary to Plaintiffs' suggestion, Paragraph B(16) does not prohibit the State from informing the enrollee that the expedited appeal will proceed faster if they obtain a physician certification. Paragraph B(16) simply prohibits the State from requiring the enrollee to get the certification. As a result, as long as the question is clear that the enrollee may, but is not required to, obtain the certification, the form is acceptable. As a result, Plaintiffs' request to remove the physician certification block is denied.

For the reasons outlined above, Plaintiffs' requests regarding the Time-Sensitive Care Rule and the Medical Appeal Form are GRANTED in part and DENIED in part.[8]

II. CONCLUSION

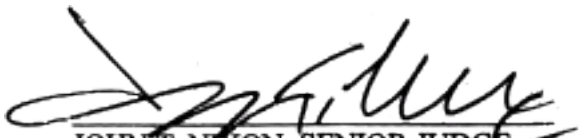
The Court APPROVES the modifications to which the parties have agreed. (See Doc. No. 1356 (highlighting agreed upon text in yellow).) The Court APPROVES the remaining

[8] Plaintiffs' request to require an expedited appeal for cases in which a MCC has the discretionary option to cover an otherwise non-covered service when the MCC determines the service is "cost-effective," is DENIED.

modifications, as listed above. Within ten days of the entry of this Order, the parties are ORDERED to submit for the Court's final approval a copy of the revised Consent Decree, which includes the agreed upon and Court approved modifications, the notices, as revised by this Order, as well as proposals for Paragraph C(20)(a).

It is so ORDERED.

Entered this the __13th_____ day of_____July_____, 2006.



JOHN T. NIXON, SENIOR JUDGE
UNITED STATES DISTRICT COURT